

## REMARKS

### Summary of the Invention

The invention features methods for inducing myelination of neural cells by glial cells.

The methods involve contacting glial cells with amino acids 358-422 (SEQ ID NO: 154), amino acids 350-411 (SEQ ID NO: 188), and amino acids 350-422 (SEQ ID NO: 189), respectively, of human GGF2; amino acids 362-411 (SEQ ID NO: 151) of bovine GGF2; and amino acids 54-103 (encoded by SEQ ID NO: 150) and SEQ ID NOs: 152 and 155-159, which correspond to variably-sized sequences resulting from differentially spliced RNA transcripts encoding bovine and human glial growth factor polypeptides.

### Support for the Amendments

Support for the amendments can be found in the sequence listing (SEQ ID NO: 151 and 152).

### Summary of the Office Action

Claims 142 and 143 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 132, 136-137, and 139-142 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S.P.N. 6,204,241 (hereinafter the “241 patent”).

### Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 142 and 143 for indefiniteness for reciting SEQ ID NOs:

151 and 152 as nucleic acid sequences. Applicants have amended claims 142 and 143 to recite SEQ ID NOs: 151 and 152 as amino acid sequences. Applicants respectfully request that the rejection of claims 142 and 143 now be withdrawn.

#### Obviousness-Type Double Patenting Rejection

The Examiner rejects claims 132, 136-137, and 139-142 for obviousness-type double patenting over claim 11 of the '241 patent. The Examiner states that:

although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptides administered by the process steps recited in the instant application...are all contained within SEQ ID NO: 170 of claim 11 of the instant patent.

Applicants respectfully traverse the rejection.

The M.P.E.P. § 804(II)(B)(1) states that “the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in a patent? If the answer is yes, then an ‘obviousness-type ‘ nonstatutory double patenting rejection may be appropriate.” Furthermore, the Federal Circuit Court held in *In re Kaplan* (789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986)) that:

to establish “obviousness-type” double patenting as to an attempt to obtain a patent on a variation of an invention claimed in a prior patent, there must be some clear evidence to establish why the variation would have been obvious. The evidence must relate to material that qualifies as “prior art.”

The Examiner, by stating that the polypeptides “are all contained within SEQ ID NO: 170 of claim 11 of the instant patent,” suggests that the use of the polypeptides of the instant invention would be an obvious variation in a method for inducing myelination of neural cells by glial cells,

however, the Examiner has failed to provide any prior art evidence to support this assertion, as required, *Supra*. Applicants point out that SEQ ID NOs: 152, 155-159, and amino acids 54-103 of SEQ ID NO: 150, which represent bovine and human glial growth factor polypeptides produced from variably-sized, differentially spliced RNA transcripts (see page 34, lines 2-22, of the specification) and are recited in claims 132, 141, and 143 of the instant invention, contain sequence information that is not found in SEQ ID NO: 170. The court held in *In re Vogel* (422 F.2d 438, 164 USPQ 619 (CCPA 1970)) that “if the rejected claim defines more than an obvious variation, it is patentably distinct.” These polypeptide fragments are not provided by SEQ ID NO: 170 and one skilled in the art would not be directed to the use of these polypeptides based on the sequence disclosed in SEQ ID NO: 170, therefore, these polypeptides do not constitute an obvious variation and are patentably distinct.

Applicants also argue that the Examiner has not met the burden of showing that SEQ ID NO: 151, which corresponds to amino acids 362-411, of bovine GGF2, and SEQ ID NOs: 154, 188, and 189, which correspond to amino acids 358-422, amino acids 350-411, and amino acids 350-422, respectively of human GGF2, and which are recited in claims 132, 136, 137, and 139-142 of the instant application, constitute an obvious variation based on claim 11 of the ‘241 patent. First, claim 11 of the ‘241 patent requires that the polypeptide contain amino acids 51-422. Second, the polypeptides of the instant invention lack over 80% of the sequence information contained within SEQ ID NO: 170. There is no suggestion in claim 11 of the ‘241 patent to use smaller polypeptide fragments in the method of the instant invention. Furthermore, one skilled in the art would not be directed, based solely on claim 11 of the ‘241 patent, to use the specific polypeptides claimed in the instant invention. Even if it would be obvious to one

skilled in the art to test smaller polypeptides for activity, the court held in *Ecolochem Inc. v. Southern California Edison Co.* (227 F.3d 1361, 56 USPQ2d 1065 (Fed. Cir. 2000) that “‘obvious to try’ is not the standard.” Therefore, based on the foregoing remarks, Applicants respectfully request withdrawal of the rejection of claims 132, 136-137, and 139-142 for obviousness-type double patenting.

#### CONCLUSIONS

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Version with markings to show changes made

In the claims:

A marked-up version of claims 142 and 143 is presented below.

142. (Amended) The method of claim 141, wherein said amino [nucleic] acid sequence is SEQ ID NO: 151.

143. (Amended) The method of claim 141, wherein said amino [nucleic] acid sequence is SEQ ID NO: 152.